IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXO GROUP LIMITED	:	
Plaintiff,	:	Civil Action No. 04-171-KAJ
v.	:	
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LIMITED	:	
Defendants.	:	

JOINT CLAIM CONSTRUCTION CHART
FOR U.S. PATENT NO. 5,068,249

Pursuant to Paragraph 11 of the Scheduling Order, plaintiff Glaxo Group Limited ("Glaxo") and defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Limited (collectively, "Teva") submit this joint claim construction chart of claim elements from U.S. Patent No. 5,068,249 (the " '249 patent") that are in dispute. This chart includes each party's proposed constructions of the disputed claim elements with citations only to the intrinsic evidence in support of their respective proposed constructions. A copy of the '249 patent and those portions of the intrinsic record relied upon are attached hereto as Exhibits 1-3:

- Exhibit 1: certified copy of the '249 patent (G000001-4);
- Exhibit 2: certified copy of U.S. P.T.O. prosecution history for Glaxo's 131,442 application filed December 11, 1987 (G000236-308); and

- Exhibit 3: certified copy of U.S. P.T.O. prosecution history for Glaxo's 344,620 application filed April 28, 1989 and for Glaxo's 494,804 application filed March 14, 1990, which led to the issuance of the '249 patent (G000111-235).

Glaxo's and Teva's Joint Claim Construction Chart
for U.S. Patent No. 5,068,249

Claim Element	Glaxo's Position	Teva's Position
Claims 1-12 "a stabilizing effective amount of"	Glaxo's Proposed Construction: An amount sufficient to enhance the stability of the ranitidine active ingredient in an aqueous formulation for oral administration. Intrinsic Evidence: **'249 patent, claim 1 (Ex. 1):** "A pharmaceutical composition which is an aqueous formulation for oral administration of an effective amount of ranitidine and/or one or more physiological acceptable salts thereof, said formulation comprising a stabilizing effective amount of ethanol and said composition having a pH in the range of 6.5 to 7.5." **'249 patent, Col. 1:23-44 (Ex. 1):** "British Patent Application No. GB 2142820A describes aqueous based formulations containing ranitidine and/or one or more of its physiologically acceptable salts thereof having a pH within the range of 6.5-7.5. . . . For oral administration the formulation also contains hydroxypropylmethyl cellulose as a viscosity enhancing agent, a preservative (parabens), a sweetening agent and a flavour. These compositions have a significantly greater shelf-life over those in British Patent No. 1565966.	Teva's Proposed Construction: An amount of a stabilizer that is sufficient to cause a statistically significant increase in the time it takes for an aqueous formulation containing ranitidine hydrochloride to lose 5 percent of the ranitidine present (the "T95" value) as compared to the same formulation without the stabilizer. Intrinsic Evidence: **'249 patent, claim 1 (Ex. 1):** "A pharmaceutical composition which is an aqueous formulation for oral administration of an effective amount of ranitidine and/or one or more physiological acceptable salts thereof, said formulation comprising a stabilizing effective amount of ethanol and said composition having a pH in the range of 6.5 to 7.5." **'249 patent, Col. 1:40-44 (Ex. 1):** "We have now surprisingly found that the *stability of ranitidine* in aqueous based formulations and more particularly aqueous based formulations for oral administration *may be substantially enhanced* by the addition of ethanol to the formulation." (Emphasis added).

Claim Element	Glaxo's Position	Teva's Position
	We have now surprisingly found that the *stability of ranitidine* in aqueous based formulations and more particularly aqueous based formulations for oral administration *may be substantially enhanced* by the addition of ethanol to the formulation." (Emphasis added). **'249 patent, Col. 1:54-60 (Ex. 1):** "The amount of ethanol present in the formulation is such that the resulting formulation has *the enhanced stability*. Preferably the amount of ethanol in the composition on a weight/volume basis of the complete formulation, is within the range 2.5% to 10%, and more particularly is between 5 to 10% w/v, more especially 7-8% w/v." (Emphasis added). **'249 patent, Col. 2:47-65 (Ex. 1):** "An illustrative example of a formulation according to the invention is as follows. In this example the relative proportions of ranitidine hydrochloride and the buffer salts are such that the formulation has a pH of approximately 7. Ranitidine oral liquid formulation (150 mg/10ml) expressed as free base % w/v Ranitidine hydrochloride 1.68 Ethanol 7.5 Potassium dihydrogen orthophosphate 0.095	**'249 patent, Col. 1:54-60 (Ex. 1):** "The amount of *ethanol* present in the formulation is such that the resulting formulation has *the enhanced stability*. Preferably the amount of *ethanol* in the composition on a weight/volume basis of the complete formulation, is within the range 2.5% to 10%, and more particularly is between 5 to 10% w/v, more especially 7-8% w/v." (Emphasis added). **'249 prosecution history, Amendment dated October 30, 1989 (Ex. 3, G000139-59):** "1. (Amended) A pharmaceutical composition which is an aqueous formulation for oral administration of ranitidine and/or one or more physiologically acceptable salts thereof, said formulation also containing a stabilizing effective amount of ethanol and said composition having a pH in the range of 6.5 to 7.5. (G00139). "More particularly, claims 1 and 4 have been combined and *the amount of ethanol* present has been *functionally defined*." (10/30/89 Amendment, Ex. 3, G000140). (Emphasis added). **'249 Prosecution History, Office Action dated January 22, 1991 (G000198-201):** "Since the GB patent teaches an aqueous composition of ranitidine, it is considered well within the state of the art to choose *ethanol* as an additive

Claim Element	Glaxo's Position	Teva's Position
	Disodium hydrogen orthophosphate anhydrous 0.350 Hydroxypropylmethylcellulose qs Preservative qs Sweetening agents qs Flavour qs Purified water BP to 100ml. " **'249 prosecution history, Office Actions dated May 5, 1988 (Ex. 2, G000263-65) and June 28, 1989 (Ex. 3, G000130-35):** "All claims should recite amounts for all ingredients." (5/5/88 Office Action, Ex. 2, G000246; 6/28/89 Office Action, Ex. 3, G000131). "The art teaches the cojoining of ranitidine and an alcohol; e.g. ethanol. The addition of a non-critical pH limit and non-critical amounts are not seen as patentable limitations to the varioues [sic] claims." (5/5/88 Office Action, Ex. 2, G000265). "The art teaches the cojoined use of use of [sic] ranitidine and an alcohol (ethanol). The claims also teach ranitidine and ethanol. The various parameters of the claims; i.e. pH and amounts are considered as choices to one skilled in the art. Such parameters have not been demonstrated as being critical and as such are considered to be within the skill of the art." (6/28/89 Office Action, Ex. 3, G000132).	which would be considered pharmaceutically acceptable when formulating this composition. Absent evidence to the contrary, the addition of *ethanol* is considered merely to be a choice among known conventional excipients." (G000200) (Emphasis added). **'249 Prosecution History, Declaration of John Hempenstall dated April 12, 1991 (G000208-211):** "5. In my laboratory it was found that for aqueous based ranitidine formujlation, *a significant* and surprising *enhancement* in the stability of ranitidine is achieved by the addition of *ethanol* to the formulation. The advantageous effect resulting from the addition of ethanol to an aqueous based ranitidine formulation can readily be determined by *comparing the stability of the ranitidine in a formulation according to the present invention and the same formulation but without the added ethanol.* " (G000209) (Emphasis added). "6. In US Serial No. 07/494804 there is provided an example of a typical ranitidine oral liquid formulation according to the invention." "Stability studies were carried out *comparing this formulation with a formulation that was identical except that it did not contain ethanol.* Samples of each formulation were stored at 30 °C, 37 °C and 45 °C for approximately 3 years and the ranitidine content measured by high performance liquid

<table>
<tr><th>Claim Element</th><th>Glaxo's Position</th><th>Teva's Position</th></tr>
<tr><td></td><td>'249 prosecution history, Amendments dated November 7, 1988 (Ex. 2, G000267-70), October 30, 1989 (Ex. 3, G000139-59) and October 31, 1990 (Ex. 3, G000173-78):

"Please amend Claim 1 as follows:

1. (Amended) A pharmaceutical composition which is an aqueous formulation of ranitidine and/or one or more physiologically acceptable salts thereof, said formulation also containing a stabilizing effective amount of ethanol and said composition having a pH in the range of 6.5 to 7.5." (11/7/88 Amendment, Ex. 2, G000267).

"Please amend Claim 1 as follows:

1. (Amended) A pharmaceutical composition which is an aqueous formulation for oral administration of ranitidine and/or one or more physiologically acceptable salts thereof, said formulation also containing a stabilizing effective amount of ethanol and said composition having a pH in the range of 6.5 to 7.5." (10/30/89 Amendment, Ex. 3, G000139).

"[T]he amount of ethanol present has been functionally defined. . . . The expression 'also containing ethanol' has been modified to specify that the amount of ethanol contained in the composition is a stabilizing amount of ethanol and this amendment is fully supported by applicant's specification, at page 2, lines 4 and 5 ['249 patent, Col. 1:54-56 (Ex.</td><td>chromatography (h.p.l.c.) against a standard, which was the corresponding formulations stored at 4 °C. At each temperature 2 samples of the formulation without ethanol, identified as Batches 1 and 2 were analysed along with 3 samples of the formulation with ethanol identified as Batches 3, 4 and 5."

"The acceptable shelf life for an aqueous formulation containing ranitidine hydrochloride is considered to be the time at which no more than 5% of the ranitidine present in the formulation has degraded. Accordingly, the figure determined from the stability studies was the time (in months) for 5% ranitidine loss calculated as the lower 95% confidence limit."

"The results are as follows:

<table>
<tr><th></th><th colspan="2">Without Ethanol</th><th colspan="3">With 7.5% Ethanol</th></tr>
<tr><th>Temperature</th><th>Batch 1</th><th>Batch 2</th><th>Batch 3</th><th>Batch 4</th><th>Batch 5</th></tr>
<tr><td>30°C</td><td>12.5</td><td>13.6</td><td>19.5</td><td>17.0</td><td>20.8</td></tr>
<tr><td>37°C</td><td>5.4</td><td>4.7</td><td>7.8</td><td>7.1</td><td>7.5</td></tr>
<tr><td>45°C</td><td>1.8</td><td>2.3</td><td>2.9</td><td>2.9</td><td>2.8</td></tr>
</table>
"

"Thus, the formulation with ethanol has an average shelf life at 30°C of 19 months compared with 13 months when ethanol is excluded from the</td></tr>
</table>

<table>
<tr><th>Claim Element</th><th>Glaxo's Position</th><th>Teva's Position</th></tr>
<tr><td></td><td>1)]." (10/30/89 Amendment, Ex. 3, G000140; see also 11/7/88 Amendment, Ex. 2, G000267-68) (emphasis added).

"Applicant most respectfully submits that the art does not teach the cojoining of ranitidine and an alcohol in a pharmaceutical composition which is an aqueous formulation for oral administration. These references do not lead one of ordinary skill in the art any way to expect that the stability of ranitidine in an aqueous oral formulation could be enhanced by the presence of ethanol and does not suggest the presence of ethanol in such compositions." (10/30/89 Amendment, Ex. 3, G000141-42; see also 11/7/88 Amendment, Ex. 2, G000268-69; 11/31/90 Amendment, Ex. 3, G000175) (emphasis added).

"However, there is no teaching whatever [in Chemical Abstract 97 61014G] that the stability of ranitidine or its salts as an aqueous formulation for oral administration is enhanced by the presence of ethanol and no suggestion that ethanol should be included in pharmaceutical formulations containing ranitidine as presently claimed." (10/30/89 Amendment, Ex. 3, G000142; see also 11/7/88 Amendment, Ex. 2, G000269; 10/31/90 Amendment, Ex. 3, G000175) (emphasis added).

"Applicant wishes to reiterate that the stability of a pharmaceutical formulation for oral administration is the most important factor and enhancing the stability of the active ingredient of such formulations is</td><td>formulation. This is a highly significant and valuable improvement."

"The stability of oral liquid formulations as described above except containing varying amounts of ethanol was also studied at 37°C and 45°C. The clear advantageous effects of the presence of ethanol can be seen from the following table which gives the time (in months) for 5% ranitidine loss (calculated as the lower 95% confidence limit)."

<table>
<tr><td>"Temperature</td><td colspan="5">% Ethanol</td></tr>
<tr><td></td><td>0</td><td>2.5</td><td>5.0</td><td>7.5</td><td>10.0</td></tr>
<tr><td>37°C</td><td>5.9</td><td>7.2</td><td>7.6</td><td>7.7</td><td>6.4</td></tr>
<tr><td>45°C</td><td>2.1</td><td>2.4</td><td>2.4</td><td>2.6</td><td>2.7"</td></tr>
</table>
(5/10/91 Request for Reconsideration, Ex. 2, ¶¶ 5 and 6 at G000209-211) (Emphasis added).</td></tr>
</table>

Claim Element	Glaxo's Position	Teva's Position
	always an objective. Thus, in the development of any pharmaceutical formulation, it is necessary to ensure that the *drug substance is stable* within the formulation and this is necessary for two main reasons. Firstly, the drug substance must be stable in order to ensure that the patient is receiving the correct dosage of the drug. Secondly, it is important to ensure that the patient is not receiving significant amounts of breakdown products arising from the *degradation of the drug substance in the formulation*. This second point is particularly important since it is not always possible to identify fully all of the breakdown products that may occur. Consequently, the chronic toxicity of all of the various compounds arising from the *breakdown of the drug substance* cannot be determined. In practice, *degradation of the drug substance* within a formulation usually occurs upon storage and is often dependent upon a number of factors including temperature and time of storage. Any improvement that can be made in *enhancing the stability of the drug substance* can only benefit the patient since it ensures more accurate dosage and the intake of less breakdown products. In addition, *enhancement of the stability of the drug substances* also benefit from the economic point of view in that it *increases the effective shelf life of the product*." (10/30/89 Amendment, Ex. 3, G000143-44; *see also* 10/31/90 Amendment, Ex. 3, G000176) (emphasis added).	

Claim Element	Glaxo's Position	Teva's Position
	'249 prosecution history, Office Action dated January 22, 1991 (Ex. 3, G000198-201): "It has not been demonstrated in the record, by means of experimental data, that the applicant's invention produces any unexpected results. The disclosure, as presented, is insufficient to overcome the prior art without the aid of experimental data to show a definite improvement over the GB patent [GB 2142820A to Padfield]. Since the GB patent teaches an aqueous composition of ranitidine, it is considered well within the state of the art to choose ethanol as an additive which would be considered pharmaceutically acceptable when formulating this composition. Absent evidence to the contrary, the addition of ethanol is considered merely to be a choice among known conventional excipients." (1/22/91 Office Action, Ex. 3, G000200). **'249 prosecution history, Request for Reconsideration dated May 10, 1991 (Ex. 3, G000204-11):** "Applicant submits herewith a Declaration of Dr. John Hempenstall which provides convincing evidence that the compositions of the present invention *show a quite unexpected advantage over the teachings of GB-A-2142820 in terms of the stability of the ranitidine in the composition*. In this connection, it is noted that the liquid formulation without ethanol which is used in the Declaration for purposes of comparison is the same as the	

Claim Element	Glaxo's Position	Teva's Position
	formulation of Example 3 of Padfield et al. [GB-A-2142820]. Accordingly, *the Declaration presents a direct comparison between a composition according to the present invention and a composition according to the prior art.* . . . Applicant acknowledges that ethanol has previously been used in pharmaceutical compositions. However, the purpose for which ethanol has been included has been either as *a solvent or as a preservative against bacterial contamination.* There was, however, no reason to suppose that either of these functions of ethanol would have had any beneficial effects in terms of *limiting the degradation of ranitidine* in aqueous formulations thereof." (5/10/91 Request for Reconsideration, Ex. 3, G000205) (emphasis added). **'249 prosecution history, Declaration of Dr. John Hempenstall executed April 12, 1991 (Ex. 3, G000208-11):** "5. In my laboratory it was found that for an aqueous based ranitidine formulation, *a significant and surprising enhancement in the stability of ranitidine* is achieved by the addition of ethanol to the formulation. * * * 7. The above results clearly show that ethanol has a *beneficial effect upon the stability of ranitidine* in aqueous based formulations and furthermore I am not aware of any teaching in the art that would lead me to	

Claim Element	Glaxo's Position	Teva's Position
	expect such an effect." (5/10/91 Request for Reconsideration, Ex. 3, ¶¶ 5 and 7 at G000209, 211) (emphasis added).	
Claims 1-12 "ethanol"	Glaxo's Proposed Construction: An organic compound comprising a lower aliphatic hydrocarbon group having two carbon atoms and one -OH group with the chemical formula CH_3-CH_2-OH (or C_2H_5OH) and a molecular weight of 46.07. Intrinsic Evidence: **'249 patent, Col. 1:40-60 (Ex. 1):** "We have now surprisingly found that the stability of ranitidine in aqueous based formulations and more particularly aqueous based formulations for oral administration may be substantially enhanced by the addition of *ethanol* to the formulation. Thus the present invention provides a pharmaceutical composition which is an aqueous formulation of ranitidine and/or one or more physiologically acceptable salts thereof also containing *ethanol*. The aqueous formulation is prepared *using ingredients of a purity* such that it is suitable for administration to patients and will in general contain at least one conventional pharmaceutical excipients in addition to	Teva's Proposed Construction: A chemical of the nomenclature CH_3CH_2OH, namely ethanol. Intrinsic Evidence: **'249 Patent Abstract (Ex. 1):** "The stability of aqueous formulations of ranitidine or a plysiologicdally acceptable salt thereof is enhanced by the addition of *ethanol*." (Emphasis added). **'249 patent, Col. 1:40-44 (Ex. 1):** "We have now surprisingly found that the stability of ranitidine in aqueous based formulations and more particularly aqueous based formulations for oral administration may be substantially enhanced by the addition of *ethanol* to the formulation." (Emphasis added). **'249 patent, Col. 1:54-56 (Ex. 1):** "The amount of *ethanol* present in the formulation is such that the resulting formulation has the enhanced

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<tr><td></td><td>the ethanol and ranitidine and/or physiologically acceptable salts thereof.

The amount of ethanol present in the formulation is such that the resulting formulation has the enhanced stability. Preferably the amount of ethanol in the composition on a weight/volume basis of the complete formulation, is within the range of 2.5% to 10%, and more particularly is between 5 to 10% w/v, more especially 7-8% w/v." (Emphasis added).

'249 prosecution history, Amendments dated October 30, 1989 (Ex. 3, G0000139-59) and October 31, 1990 (Ex. 3, G0000173-78):

"At the outset, applicant specifically traverses the statement in the Official Action that the references relied upon by the Examiner teach the cojoining of ranitidine and an alcohol, e.g., ethanol. Applicant most respectfully submits that the art does not teach the cojoining of ranitidine and an alcohol in a pharmaceutical composition which is an aqueous formulation for oral administration." (10/30/89 Amendment, Ex. 3, G000141; see also 10/31/90 Amendment, Ex. 3, G000175) (emphasis added).</td><td>stability." (Emphasis added).

'249 patent, Col. 1:56-60 (Ex. 1):

"Preferably the amount of ethanol in the composition on a weight/volume basis of the complete formulation, is within the range 2.5% to 10%, and more particularly is between 5 to 10% w/v, more especially 7-8% w/v." (Emphasis added).

'249 patent, Col. 2:53-65 (Ex. 1):

"Ranitidine oral liquid formulation (150 mg/10ml) expressed as free base
% w/v
Ranitidine hydrochloride 1.68
Ethanol 7.5
Potassium dihydrogen orthophosphate 0.095
Disodium hydrogen orthophosphate anhydrous 0.350
Hydroxypropylmethylcellulose qs
Preservative qs
Sweetening agents qs
Flavour qs
Purified water BP to 100ml."
(Emphasis added).

'249 prosecution history, Office Action dated May 5, 1988 (Ex. 2, G000263-65):</td></tr>
</table>

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		"Claim 1-10 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention." (G000264). "Claim 1-12 rejected under 35 U.S.C. 112, first paragraph, as the disclosure is enabling only for claims limited in accordance with the entire disclosure. (G000264). "The art teaches the cojoining of ranitidine and an *alcohol*; e.g. *ethanol*. The addition of a non-critical pH limit and non-critical amounts are not seen as patentable limitations to the varioues [sic] claims." (5/5/88 Office Action, Ex. 2, G000265) (Emphasis added). **'249 prosecution history, Amendments dated November 7, 1988 (Ex. 2, G000267-70), and October 30, 1989 (Ex. 3, G000139-59):** "Please amend Claim 1 as follows: 1. (Amended) A pharmaceutical composition which is an aqueous formulation of ranitidine and/or one or more physiologically acceptable salts thereof, said formulation also containing a stabilizing effective amount of *ethanol* and said composition having a pH in the range of 6.5 to 7.5." (11/7/88 Amendment, Ex. 2, G000267) (Emphasis added).

Claim Element	Glaxo's Position	Teva's Position
		'249 prosecution history, Amendment dated October 30, 1989 (Ex. 3, G000139-59): "1. (Amended) A pharmaceutical composition which is an aqueous formulation for oral administration of ranitidine and/or one or more physiologically acceptable salts thereof, said formulation also containing a stabilizing effective amount of *ethanol* and said composition having a pH in the range of 6.5 to 7.5. (G00139). (Emphasis added). "More particularly, claims 1 and 4 have been combined and the amount of *ethanol* present has been functionally defined." (10/30/89 Amendment, Ex. 3, G000140) (Emphasis added). "These references do not lead one of ordinary skill in the art any way to expect that the stability of ranitidine in an aqueous oral formulation could be enhanced by the presence of *ethanol* and does not suggest the presence of *ethanol* in such compositions." (10/30/89 Amendment, Ex. 3, G000141-142) (Emphasis added). "Applicant most respectfully submits that all that one of ordinary skill in the art can infer from this reference is that ranitidine hydrochloride must be reasonably stable in *ethanol* since *ethanol* is used as a solvent for recrystallization." (10/30/89 Amendment, Ex. 3, G000142) (Emphasis added). **'249 Prosecution History, Office Action dated**

Claim Element	Glaxo's Position	Teva's Position
		November 14, 1989 (Ex. 3, G000160-162): "This art clearly precludes applicants claims to ranitidine and *ETOH*." (G000161) (Emphasis added). "As for the allegation of enhanced stability, it has not been demonstated for the compositions urged as contrasted with any of other pH parameters." (G000161) **'249 Prosecution History, Amendment dates October 31, 1990 (Ex. 3, G000173-78):** "These references do not lead one of ordinary skill in the art in any way to expect that stability of ranitidine in an aqueous oral formulation could be enhanced by the presence of *ethanol* and does not suggest the presence of *ethanol* in such compositions." (G000175) (Emphasis added). **'249 Prosecution History, Official Action dated January 22, 1999 (G00198-201):** "It has not been demonstrated in the record, by means of experimental data, that the applicant's invention produces any unexpected results. The disclosure, as presented, is insufficient to overcome the prior art without the aid of experimental data to show a definite improvement over the GB patent. Since the GB patent teaches aqueous composition of ranitidine, it is considered well within the state of the art to choose *ethanol* as an additive which would be

Claim Element	Glaxo's Position	Teva's Position
		considered pharmaceutically acceptable when formulating this composition. Absent evidence to the contrary, the addition of *ethanol is considered merely to be a choice among known conventional excipients*." (G000200) (Emphasis added). **'249 Prosecution History, Request for Reconsideration dated May 10, 1991 (G000204-207)** "Furthermore, there is clear disincentive against the use of *ethanol* in aqueous formulations. Thus, an important use of ranitidine is in the treatment of peptic ulcers and related conditions, and it is well known that *alcohol* (i.e. *ethanol*) can aggravate such conditions." (G000206) (Emphasis added). "However, the fact that *ethanol* has a known effect in aggravating one of the main conditions that the compositions according to the invention are intended to treat would be a clear disincentive to including *ethanol without knowledge of the beneficial effects on stability. This knowledge is, of course, provided only by the present invention*." (G000206) (Emphasis added). **'249 Prosecution History, Declaration of John Hempenstall dated April 12, 1991 (G000208-211):** "5. In my laboratory it was found that for aqueous based ranitidine formulation, a significant and surprising enhancement in the stability of ranitidine

Claim Element	Glaxo's Position	Teva's Position
		is achieved by the addition of *ethanol* to the formulation." (G000209) (Emphasis added).
Claim 2 (dependent on Claim 1) "2.5% to 10% weight/ volume ethanol"	Glaxo's Proposed Construction: 2.5% to 10% weight/volume ethanol sufficient to enhance the stability of the ranitidine active ingredient in the aqueous formulation for oral administration. Intrinsic Evidence: **'249 patent, claim 1 (Ex. 1):** "A pharmaceutical composition which is an aqueous formulation for oral administration of an effective amount of ranitidine and/or one or more physiological acceptable salts thereof, said formulation comprising *a stabilizing effective amount of* ethanol and said composition having a pH in the range of 6.5 to 7.5." (Emphasis added). **'249 patent, claim 2 (Ex. 1):** "A pharmaceutical composition according to claim 1 containing 2.5% to 10% weight/volume ethanol based on the complete formulation." Glaxo incorporates by reference all of the intrinsic	Teva's Proposed Construction: 2.5% to 10% weight/volume ethanol. Intrinsic Evidence: **'249 patent, claim 2 (Ex. 1):** "2. A pharmaceutical composition according to claim 1 containing 2.5% to 10% weight/volume ethanol based on the complete formulation." **'249 patent, claim 3 (Ex. 1):** "3. A pharmaceutical composition according to claim 1 containing 7% to 8% weight/volume ethanol based on the complete formulation." **'249 patent, claim 11 (Ex. 1):** 11. A pharmaceutical composition which is an aqueous formulation of ranitidine suitable for oral administration containing 150 mg ranitidine per 10 ml dose expressed as free base, said formulation having a pH in the range 7.0 to 7.3 and also